Research Article

Comparison of two protocols for management of neonate delivered by mothers with PROM

Pedram Niknafs¹, Babak Teimoorzadeh*, Nozar Nakhaee², Bahareh Bahman-Bijari¹ and Elahe Norouzi, MD¹

¹Afsalipour Medical Center; ²Kerman University of Medicine, Neurosci Res Ctr, Kerman, Iran

ABSTRACT

Objective: Premature rupture of the fetal membranes (PROM) is defined as the rupture of amniotic membranes with release of the amniotic fluid more than 1 hour prior to the onset of labor. This study was designed to evaluate two different protocols in management of neonates born to mother with PROM by comparing outcomes.

Methods: This study was a experimental study. 138 neonates who born to mother with PROM are managed according to two different protocols so called scoring protocol (group I) and protocol of America Academy of Pediatrics (group II). The variables and main outcomes of this study were gestational age, gender, birth weight, duration of PROM, Chorioamnionitis, sign of sepsis, admission, lab test request.

Findings: From 67 neonates in group I, 53.7% cases and from 71 neonates in group II, 52.1% cases were girl (p = 0.849). Gestational age in group I was 35.7 ± 2.4 weeks and in group II was 36.3 ± 2.3 weeks (p = 0.127). In group I duration of PROM was 89.66 hours and in group II was 50.47 hours (p < 0.001). From 67 neonates in group I, 25.4% cases and from 71 neonates in group II 12.7% cases were admitted (p = 0.057)

Conclusion: According to the finding the admission rate in protocol II was less than protocol I, so it may show the effectiveness of this protocol.

Key Words: Premature rupture of membrane, Management, Neonate, Sepsis, Admission, Antibiotic.

INTRODUCTION

Premature rupture of the fetal membranes (PROM) is defined as the rupture of amniotic membranes with release of the amniotic fluid more than 1 hour prior to the onset of labor. PROM occurs in approximately 3% of pregnancies and is responsible for a third of all preterm births (1). Gestational age at delivery is the primary determinant of the frequency and severity of neonatal complication after PROM. Respiratory distress syndrome, necrotizing enterocolitis, intraventricular hemorrhage and sepsis are the most common serious acute morbidities (1,2).

Early preterm birth can lead to long – term complication, including chronic lung disease, visual or hearing difficulties, mental retardation, development and motor delay and cerebral palsy (1,2). Pulmonary hypoplasia is a serious complication of PROM and mortality from this condition ranges between 50-100% (3,4,5,6). Lethal
pulmonary hypoplasia is uncommon with PROM after 24 to 26 weeks' gestation\textsuperscript{6,7,8}.

The pattern of fetal restriction deformities occurring subsequent to PROM are similar to those seen with Potter syndrome\textsuperscript{9}.

The aim of this study was to verify the effectiveness of treatment protocols by comparing the outcomes of neonates born to mothers with PROM with two different therapeutic protocols which we called protocol I and protocol II.

**Subjects and methods**

This study was a clinical trial to compare the management of neonates who born to mothers with PROM, between two groups of patients being treated in neonatal intensive care unit (NICU) in Afzalipour Medical Center in Kerman with different therapeutic protocols. Patient assessment was done by fellowship in neonatology.

The sample size with using the formula of the

\[
\frac{32}{\text{Effect size}^2}
\]

and consideration of the treatment effect size = 0.5 (moderate effect size), was 64 people in each group\textsuperscript{10}.

All the infants born to mothers with PROM were transferred to the neonatal unit with transfer sheet with information about gestational age, maternal age, mode of delivery, Apgar score, kind and dose and duration of antibiotic received by mother, presence or absence of chorioamnionitis, sex, resuscitation, duration of rupture of fetal membranes.

The neonates were treated on the basis of two treatment protocols, one and necessary information was recorded.

If indicated, the neonate was admitted and information was obtained from patient records, in the cases that were under observation, 48 hours later, the neonates were visited by the subspecialty resident and additional information were recorded.

In this study two treatment protocols are described. The first protocol (scoring protocol – protocol I) was published by St. Geme JW Jr in 1984 (table 1), in this study, it will be remembered as a protocol I (table 1)\textsuperscript{11}.

In this protocol, ill neonates were admitted and full sepsis workup was done, but neonates who were not ill, were rated according to the criteria of gestational age, clinical and pathological evidence of chorioamnionitis, Apgar 5 min and sex (table 1)\textsuperscript{11}.

Second treatment protocol (protocol II) was presented by the America Academy of Pediatrics in 2010 (Figure1)\textsuperscript{12}.

<table>
<thead>
<tr>
<th>RISK FACTORS</th>
<th>SCORE</th>
</tr>
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<tbody>
<tr>
<td>Gestation age&lt;34 weeks</td>
<td>2 points</td>
</tr>
<tr>
<td>Gestation age 34 to 37</td>
<td>1 “</td>
</tr>
<tr>
<td>Maternal clinical amnionitis</td>
<td>1 “</td>
</tr>
<tr>
<td>Maternal pathologic amnionitis</td>
<td>2 “</td>
</tr>
<tr>
<td>5 minute Apgar score&lt;6</td>
<td>1 “</td>
</tr>
<tr>
<td>Male sex</td>
<td>1 “</td>
</tr>
</tbody>
</table>

Score 0 to 1 point: observation only.
Score 2 point: sepsis work up excluding CSF analysis and culture, followed by observation.
Score 3 points or more: complete sepsis workup, followed by antibiotic therapy.

Chorioamnionitis is characterized by the following\textsuperscript{11}:

1 - Mother body temperature greater than 38 °C (clinical chorioamnionitis)
2 - Fetal tachycardia more than 160 beats per minute (clinical chorioamnionitis)
3 – Polymorphonuclears or bacteria in the amniotic fluid or infant’s stomach fluid. (Pathologic chorioamnionitis)
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**Figure 1.** Protocol of America Academy of Pediatrics (Protocol II)

a. Full diagnostic evaluation includes a blood culture, a complete blood count (CBC) including white blood cell differential and platelet counts, chest radiograph (if respiratory abnormalities are present), and lumbar puncture (if patient is stable enough to tolerate procedure and sepsis is suspected).

b. Antibiotic therapy should be directed toward the most common causes of neonatal sepsis, including intravenous ampicillin for GBS and coverage for other organisms (including Escherichia coli and other gram-negative pathogens and should take into account local antibiotic resistance patterns.)

c. Consultation with obstetric providers is important to determine the level of clinical suspicion for chorioamnionitis. Chorioamnionitis is diagnosed clinically and some of the signs are nonspecific.

d. Limited evaluation includes blood culture (at birth) and CBC with differential and platelets (at birth and/or at 6–12 hours of life).

e. GBS prophylaxis is indicated if 1 or more of the following is true:
   1. Mother is GBS-positive within the preceding 5 weeks;
   2. GBS status is unknown and there are 1 or more intrapartum risk factors, including 37 weeks’ gestation, rupture of membranes for 18 hours, or temperature of 100.4°F (38.0°C);
   3. GBS bacteriuria during current pregnancy.

f. If signs of sepsis develop, a full diagnostic evaluation should be conducted and antibiotic therapy initiated.

**Including factor:**
All infants who were born to mothers with PROM in Afzaliipour Medical Center

**Excluding factor:**
1. The neonates were accompanied with any congenital or chromosomal malformations.
2. The neonates were discharged with their own parent consent.
The neonates were referred to the other centers due to treatment or other medical complications.

In this study, endpoint is the recovery and hospital discharge or death.

The variables of this study were gestational age, gender, birth weight, duration of rupture of membrane, mode of delivery, resuscitation, chorioamnionitis, sign of sepsis, admission, length of hospital stay, lab test request and lumbar puncture.

In order to compare quantitative and nominal data in two groups, respectively, t-test (or nonparametric equivalent) and chi-square were used. All data were analyzed with SPSS 20 software.

In this study the significance level which was considered for all tests was p<0.05.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Comparison of background and Clinical variables of the neonates in two protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>variable</td>
<td>Protocol 1</td>
</tr>
<tr>
<td></td>
<td>Protoco l 1</td>
</tr>
<tr>
<td>Gestational age(week)</td>
<td>35.7±2.4</td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>2535±661.41</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>53.7%</td>
</tr>
<tr>
<td>Mode of delivery(NVD)</td>
<td>55.2%</td>
</tr>
<tr>
<td>CPR (n)</td>
<td>4</td>
</tr>
<tr>
<td>Duration of PROM (hour)</td>
<td>89.66</td>
</tr>
<tr>
<td>Chorioamnionitis</td>
<td>11.9%</td>
</tr>
<tr>
<td>Sign of sepsis</td>
<td>13.4%</td>
</tr>
<tr>
<td>Admission</td>
<td>25.4%</td>
</tr>
<tr>
<td>Duration of hospital stay (day)</td>
<td>5.18</td>
</tr>
<tr>
<td>Lab test</td>
<td>40%</td>
</tr>
<tr>
<td>Lumbar Puncture</td>
<td>100%</td>
</tr>
</tbody>
</table>

DISCUSSION

Among the problems that premature rupture of membrane makes to mother and neonate, is risk of infection (chorioamnionitis in mother and sepsis in neonate), that is observed in a significant number of babies born to mothers with premature rupture of the membrane. So any attempt for finding a method for early diagnosis of neonatal infection and identify infants at risk of infection and hospitalization and treatment of sepsis is worthwhile. Hospitalization can affect both mother and neonate normal life and increase possibility...
of infant and maternal separation and can cause many complications, including physical and emotional complications and have cost to families and society. This study compared two treatment methods with neonates born to mothers with premature rupture of membrane in the case of early diagnosis and treatment of possible infection. Unfortunately, there was not an article earlier in this issue. Comparing the results of these two groups shows that there is no significant difference in neonates at two groups in the case of sex, birth weight, gestational age, mode of delivery, need to CPR, the frequency of symptoms of chorioamnionitis and sepsis; so we can compare these two groups.

Comparing the results of these two groups shows that in group I 11.9% and in group II 5.6% of mothers have chorioamnionitis. The incidence of chorioamnionitis was 13-60% in study that done by Tanya M in USA \((13)\). This low incidence in our study could be due to better supervision of mothers with PROM.

Comparing the results of these two groups shows that average duration of fetal membrane rupture in the protocol I was 89.66 hours and in protocol II was 50.47 hours and difference was significant between the two groups \((P<0.001)\). This significant difference between the two groups is result of differences between the two protocols, with in the protocol I, neonate born to mothers with premature rupture of membrane above 18 hours are evaluated, but in the protocols II neonates born mothers with premature rupture of membrane with any duration of PROM, are evaluated. This can show protocol II is more comprehensive than protocol I, in protocol II all neonates born to mothers with premature rupture of the membrane, are evaluated. According to the study which published by Wagner MV in 1989 delivery within 1 week is the most common outcome after PROM at any gestational age \((14)\).

Comparing the results of the two groups shows that in group I 11% and in the group II 9.8% of neonates had clinical signs of sepsis and difference was not significant between the two \((P = 0.111)\). In a study conducted in Egypt in 2009 by Nabhan AF, 3% of neonates had probable early – onset neonatal sepsis \((15)\).

Comparing the results of the two groups shows that in Group I 25.4% and in the group II 12.7% of neonates were admitted and the difference was statistically nearly significant \((P = 0.057)\). This significant difference, despite no difference in the prevalence of symptoms of sepsis between the two groups could be due to that in the protocol I male gender are involved in the ratings. Despite of that male gender is a risk factor for sepsis, but that does not seem to be an important factor for admission. In the group II, the male gender did not have any role in admission and just symptoms of sepsis and maternal chorioamnionitis (common between the two groups) are involved in the neonate’s admission, so frequency of admission in protocol II is lower than protocol I and according to this issue that frequency of positive blood cultures in both groups was zero, It appears that the protocol II is more efficient rather than protocol I in management with infants born to mothers with premature rupture of membranes. In a study in Egypt by Nabhan AF 5.2% of neonates born to mother with PROM were admitted \((15)\).

Comparing the results of the two groups shows that in group I 40% and in group II 33.9% of underobserved neonates, CBC test, blood cultures were obtained, and the difference was not significant \((P = 0.503)\). According to the two treatment protocols, it seems that request of lab test in protocol II should be significantly lower rather than the group I. This ambiguity can be explained in this way that in the protocol II,
indication of lab test is the duration that mother received antibiotics. If duration is over 4 hours, no need to get lab tests, regardless of gestational age, duration of premature rupture of the membrane and just necessary to under observed neonate for 48 hours. Considering that in management mothers with premature rupture of membranes had delivered in Azalipoor hospital, Only mothers received antibiotic who had duration of premature rupture of membrane over 12 hours. So we requested lab test for neonates whose their mothers had duration of PROM less than 12 hours and were premature. If these mothers receive antibiotics from the onset of fetal membrane rupture, frequency of lab test request will decreases significantly.

CONCLUSION
According to the above mentioned, In management with neonates born to mothers with premature rupture of membrane, all neonates are investigated in protocol I and admission rate is lower in this protocol. It seems that protocol I is more comprehensive rather than protocol I and protocol II is recommended in management of these neonates. Also it is recommended that a study be designed that antibiotics should be start since the occurrence of rupture of membrane and it’s effect be evaluated on lab test requisition in neonates.

ACKNOWLEDGMENT
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REFERENCES:


